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*Admitted only in Maryland
*Admitted only in Virginia
•Practice limited to
Federal Agencies

October 27, 2004

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1646

Re: U.S. Utility Patent Application
Application No. 10/809,790; Filed: March 26, 2004
For: Targeted MHC Class I Alpha3 Vaccine Delivery Systems
Inventors: ZAUDERER *et al.*
Our Ref: 1843.0120001/EKS/AJK

Sir:

Transmitted herewith for appropriate action are the following documents:

1. SKGF Cover Letter;
2. Information Disclosure Statement;
3. A listing of the cited documents on form PTO-1449;
4. Copies of the cited documents (AL1-AP1, AR1-AT1, AR2-AT2, AR3-AT3, AR4-AT4, AR5-AT5, AR6-AT6, AR7-AT7, AR8-AT8, AR9-AT9, AR10); and
5. Return postcard.

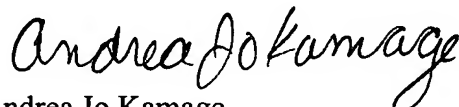
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
October 27, 2004
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Andrea Jo Kamage
Agent for Applicants
Registration No. 43,703

AJK/jk
Enclosures

326939v1



UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Zauderer *et al.*

Appl. No.: 10/809,790

Filed: March 26, 2004

For: **Targeted MHC Class I Alpha3
Vaccine Delivery System**

Confirmation No.: 7155

Art Unit: 1646

Examiner: *To be assigned*

Atty. Docket: 1843.0120001/EKS/AJK

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **AA1-AI1** are not provided in accordance with the U.S. Patent and Trademark Office OG notice of August 5, 2003, which states “[t]he Office hereby waives the requirement under 37 C.F.R. § 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003.” A copy of each other document is provided.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

U.S. Patent Application No. 09/833,203, Zauderer *et al.*, filed April 12, 2001, now U.S. Published Patent Application No. 2003/0166277 and cited herewith as document **AH1**; and

U.S. Patent Application No. 10/887,230, Zauderer, M., filed July 9, 2004 and submitted herewith as document **AR10**.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

Zauderer *et al.*
Appl. No. 10/809,790

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency,
or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1843.0120001/EKS/AJKAPPLICATION NO.
10/809,790APPLICANT(S)
Zauderer *et al.*FILING DATE
March 26, 2004ART UNIT
1646

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AAI	5,635,363	06/03/1997	Altman <i>et al.</i>			02/28/1995
	ABI	6,015,884	01/18/2000	Schneck <i>et al.</i>			03/28/1997
	ACI	6,248,564	06/19/2001	Walter <i>et al.</i>			08/29/1997
	ADI	2002/0051783	05/02/2002	Savage			06/08/2001
	AEI	2002/0123108	09/05/2002	Edwards <i>et al.</i>			12/01/1995
	AFI	2002/0155447	10/24/2002	Zauderer <i>et al.</i>			04/04/2001
	AGI	6,548,067	04/15/2003	Seeman <i>et al.</i>			06/02/1995
	AHI	2003/0166277	09/04/2003	Zauderer <i>et al.</i>			04/12/2001
	AI1	6,682,741	01/27/2004	Ribaudo <i>et al.</i>			03/19/2001
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	ALI	WO 94/25610	11/10/1994	WIPO			Yes No
	AMI	WO 99/64597	12/16/1999	WIPO			Yes No
	ANI	GB 2 339 782	02/09/2000	Great Britain			Yes No
	AOI	WO 01/44296	06/21/2001	WIPO			Yes No
	API	WO 04/029206	04/08/2004	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Altman, J.D., <i>et al.</i> , "Phenotypic Analysis of Antigen-Specific T Lymphocytes," <i>Science</i> 274:94-96, American Association for the Advancement of Science (1996)
	AS	1	Bedzyk, W.D., <i>et al.</i> , "Immunological and Structural Characterization of a High Affinity Anti-fluorescein Single-Chain Antibody," <i>J. Biol. Chem.</i> 265:18615-18620, American Society for Biochemistry and Molecular Biology, Inc. (1990)
	AT	1	Boniface, J.J., <i>et al.</i> , "Initiation of Signal Transduction through the T Cell Receptor Requires the Peptide Multivalent Engagement of MHC Ligands," <i>Immunity</i> 9:459-466, Cell Press (1998)

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Burrows, G.G., <i>et al.</i> , "Two-Domain MHC Class II Molecules Form Stable Complexes with Myelin Basic Protein 69-89 Peptide That Detect and Inhibit Rat Encephalitogenic T Cells and Treat Experimental Autoimmune Encephalomyelitis," <i>J. Immunol.</i> 161: 5987-5996, American Association of Immunologists (1998)
	AS	<u>2</u>	Casares, S., <i>et al.</i> , "Antigen-specific Signaling by a Soluble, Dimeric Peptide/Major Histocompatibility Complex Class II/Fc Chimera Leading to T Helper Cell Type 2 Differentiation," <i>J. Exp. Med.</i> 190:543-553, Rockefeller University Press (1999)
	AT	<u>2</u>	Cochran, J.R., <i>et al.</i> , "The Relationship of MHC-Peptide Binding and T Cell Activation Probed Using Chemically Defined MHC Class II Oligomers," <i>Immunity</i> 12:241-250, Cell Press (2000)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>3</u>	Dal Porto, J., <i>et al.</i> , "A Soluble divalent class I major histocompatibility complex molecule inhibits alloreactive T cells at nanomolar concentrations," <i>Proc. Natl. Acad. Sci. USA</i> 90:6671-6675, National Academy of Sciences (1993)
	AS	<u>3</u>	Glick, M., <i>et al.</i> , "Novel CD8 ⁺ T Cell Antagonists Based on β_2 -Microglobulin," <i>J. Biol. Chem.</i> 277:20840-20846, American Society for Biochemistry and Molecular Biology, Inc. (June 2002)
	AT	<u>3</u>	Greten, T.F., <i>et al.</i> , "Direct visualization of antigen-specific T cells: HTLV-1 Tax11-19-specific CD8 ⁺ T cells are activated in peripheral blood and accumulate in cerebrospinal fluid from HAM/TSP patients," <i>Proc. Natl. Acad. Sci. USA</i> 95:7568-7573, National Academy of Sciences (1998)

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	AP						Yes No

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	AR	<u>4</u>	Hamad, A.R.A., <i>et al.</i> , "Potent T Cell Activation with Dimeric Peptide-Major Histocompatibility Complex Class II Ligand: The Role of CD4 Coreceptor," <i>J. Exp. Med.</i> 188:1633-1640, Rockefeller University Press (1998)
	AS	<u>4</u>	Hebert, A.M., <i>et al.</i> , "Kinetics and Thermodynamics of β 2-Microglobulin Binding to the α 3 Domain of Major Histocompatibility Complex Class I Heavy Chain," <i>Biochem.</i> 40:5233-5242, American Chemical Society (2001)
	AT	<u>4</u>	Hochman, J.H., <i>et al.</i> , "Specific Associations of Fluorescent β -2-Microglobulin with Cell Surfaces. The Affinity of Different H-2 and HLA Antigens for β -2-Microglobulin," <i>J. Immunol.</i> 140:2322-2329, American Association of Immunologists (1988)

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Morrison, S.L., <i>et al.</i> , "Production and Characterization of Genetically Engineered Antibody Molecules," <i>Clin. Chem.</i> 34:1668-1675, American Association For Clinical Chemistry (1988)
	AS	<u>5</u>	Mottez, E., <i>et al.</i> , "Cells Expressing a Major Histocompatibility Complex Class I Molecule with a Single Covalently Bound Peptide Are Highly Immunogenic," <i>J. Exp. Med.</i> 181:493-502, Rockefeller University Press (1995)
	AT	<u>5</u>	Parham, P., <i>et al.</i> , "Carbohydrate Moiety of HLA Antigens. Antigenic Properties and Amino Acid Sequences Around the Site of Glycosylation," <i>J. Biol. Chem.</i> 252:7555-7567, American Society for Biochemistry and Molecular Biology, Inc. (1977)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Parker, K.C., and Strominger, J.L., "Subunit Interactions of Class I Histocompatibility Antigens," <i>Biochem.</i> 24:5543-5550, American Chemical Society (1985)
	AS	<u>6</u>	Penichet, M.L., <i>et al.</i> , "An Antibody-Avidin Fusion Protein Specific for the Transferrin Receptor Serves as a Delivery Vehicle for Effective Brain Targeting: Initial Applications in Anti-HIV Antisense Drug Delivery to the Brain," <i>J. Immunol.</i> 163:4421-4426, American Association of Immunologists (1993)
	AT	<u>6</u>	Salter, R.D., <i>et al.</i> , "A binding site for the T-cell co-receptor CD8 on the α_3 domain of HLA-A2," <i>Nature</i> 345:41-46, Nature Publishing Group (1990)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>1</u>	Schmitt, L., <i>et al.</i> , "Catalysis of peptide dissociation from class II MHC-peptide complexes," <i>Proc. Natl. Acad. Sci. USA.</i> 96:6581-6586, National Academy of Sciences (1999)
	AS	<u>1</u>	Shin, S-U., and Morrison, S.L., "Production and Properties of Chimeric Antibody Molecules," <i>Methods Enzymol.</i> 178:459-476, Academic Press (1989)
	AT	<u>1</u>	Shin, S-U., <i>et al.</i> , "Functional and Pharmacokinetic Properties of Antibody-Avidin Fusion Proteins," <i>J. Immunol.</i> 158:4797-4804, American Association of Immunologists (1997)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>8</u>	Sidney, J. <i>et al.</i> , "Practical, biochemical and evolutionary implications of the discovery of HLA class I supermotifs," <i>Immunol. Today</i> 17:261-266, Elsevier Science (1996)
	AS	<u>8</u>	Sidney, J., <i>et al.</i> , "Majority of Peptides Binding HLA-A*0201 With High Affinity Crossreact With Other A2-Supertypes Molecules," <i>Hum. Immunol.</i> 62:1200-1216, Elsevier/North-Holland (2001)
	AT	<u>8</u>	Springer, T.A., and Strominger, J.L., "Detergent-soluble HLA antigens contain a hydrophilic region at the COOH-terminus and a penultimate hydrophobic region," <i>Proc. Natl. Acad. Sci. USA</i> 73:2481-2485, National Academy of Sciences (1976)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	9	Turner, M.J., <i>et al.</i> , "Purification of Papain-solubilized Histocompatibility Antigens from a Cultured Human Lymphoblastoid Line, RPMI 4265," <i>J. Biol. Chem.</i> 250:4512-4519, American Society for Biochemistry and Molecular Biology, Inc. (1975)
	AS	9	Whitman, M.C., <i>et al.</i> , "The isolated major histocompatibility complex class I $\alpha 3$ domain binds $\beta 2m$ and CD8 $\alpha\alpha$ dimers," <i>Mol. Immunol.</i> 37:141-149, Pergamon Press (2000)
	AT	9	Zarutskie, J.A., <i>et al.</i> , "A Conformational Change in the Human Major Histocompatibility Complex Protein HLA-DR1 Induced by Peptide Binding," <i>Biochem.</i> 38:5878-5887, American Chemical Society (1999)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>10</u>	U.S. Patent Application No. 10/887,230, Zauderer, M., filed July 9, 2004 (NOT PUBLISHED)
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